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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,720	02/15/2001	Klaus Abraham-Fuchs	P00,1222	2613

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SCHIFF HARDIN, LLP
PATENT DEPARTMENT
6600 SEARS TOWER
CHICAGO, IL 60606-6473

EXAMINER	
MAHATAN, CHANNING	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,720	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8 and 10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8 and 10-18* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1 Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 08 December 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 2-8 and 10-18. Claims 1 and 9 have been cancelled.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 2-8 and 10-18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7, 17, 18, and all claim dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The introduction of the following amendment "...each sensitive for multiple

biomolecular markers..." (claims 7 and 17); "follow-diagnostic data as a training data set" (claims 17 and 18) is considered new matter. There does not appear to be any disclosure or contemplation for new claims 17 and 18 and the amendment to claims 7. None of these concepts were found and none is apparent. Therefore, new claims 17 and 18 and the amendments to claims 2-8 and 10-16 are considered NEW MATTER.

LACK OF ENABLEMENT

Claim 2-8 and 9-18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants are to note this rejection is reapplied in view of Applicants' arguments filed 08 December 2003 pertaining to the phrases "expert system" and "expert rules".

The intent of the instantly claim network and method is for the creation of a modified diagnostic expert rule, wherein the instant claims are to a network and a method "for creating a modified diagnostic expert rule" such that "expert rules" are used in an "expert system" and a modified rule is created (having improved diagnostic value) in comparison to the "expert rule".

Applicants' response filed 08 December 2003 states:

"...the term "expert system" is a term well known to those of ordinary skill in the art (alternatively being referred to as an artificial intelligence system, neural network). In all systems of this type, the system begins with a set of rules (in this case of an expert system, these rules are "expert rules"). (page 8, lines 12-16)

"... not only does the prior art abound with appropriate examples of such expert systems, but also the level of detail of the disclosure in those references is comparable to the level of detail in the present disclosure,

thereby providing further evidence that those of ordinary skill in the art are well informed as to the manner of operation of systems of this type." (page 9, lines 8-12)

Further, Applicants' response filed 02 June 2003 stated:

"The exact nature of the expert rules, and the goal or intended result that they are to achieve, are not important to the subject matter of the invention. It is only important that at least one of the original rules be modified so as to improve the diagnostic specificity. This is an easily ascertainable standard."(page 10, lines 14-17)

It is acknowledged the language "expert system" (alternatively referred to by Applicants as a neural network) is well known to one of ordinary skill in the art, per se. While it is the general structural form of an "expert system" (neural network) that is conceptual understood it is the absence of criteria(s)/parameter(s) that the "expert system" uses to process the inputted information which lacks enablement. For example, if one does not know the criteria(s)/parameters for the modification of the expert rule how then does one create a modified expert rule as claimed (i.e. preamble)? Further, Applicants' have indicated an "expert system" "begins with a set of rules" (i.e. "expert rules"); therefore, an initial set of "expert rules" is required to practice the claimed invention. It then follows that if one does not know the initial set of "expert rules" one does not know what is modified and does not know what is utilized for comparison to determine an improvement? The specification provides no such beginning set of rules or the derivation of such, as required, for comparative evaluation of improved diagnostic value to create a modified expert rule. The specification fails to provide the criteria(s)/parameter(s) for the manner (i.e. processed in the "expert system"/neural network) in which a modified expert rule having improved diagnostic value is derived from an initial expert rule. In the absence of a beginning set of "expert rules" and the criteria(s)/parameter(s) for

modification one of skill in the art would be required to make independent decisions and judgments to: 1) derive the beginning set of "expert rules"; 2) ascertain the rules by which the "expert system" processes the information to generate a modified diagnostic expert rule that has an improved diagnostic value when compared to the beginning set of "expert rules"; and 3) test and validate the "expert rule" derivation and the process for the creation of a modified diagnostic expert rule".

Applicants are directed to Fields, Wilkinson, and Kende v. Conover and Woodward [170 USPQ 276; How-to-Make Requirement section] which states:

> "the description must place the invention in the possession of the public as fully as if the art or instrument itself had been practically and publicly employed. In order to accomplish this, it must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it appertains could construct and use it.".

Such independent decisions, judgments, tests, and validation are not considered to be routine experimentation and one of skill in the art practicing the invention would be required to use inventive skill to develop Applicants' claimed network and method.

It is noted Applicants have articulated that the creation of a "modified expert rule" with improved diagnostic value in comparison to said "expert rule" (i.e. beginning set) is an "easily ascertainable standard" to one of ordinary skill in the art. Additionally, Applicants have asserted the prior art abounds with examples of expert systems. It is therefore requested Applicants provide, by example, this "easily ascertainable standard" by determining a "modified expert rule" utilizing any of the expert systems in the prior art with the raw biochip data from Mendoza et al. Given Applicants assertion of such an "easily ascertainable standard": What is the initial set of "expert rules" of Mendoza et al.? How are these "expert rules" modified to derive a

"modified expert rule with improved diagnostic value in comparison to said expert rule used to produce said diagnostic result"?

Thus, the specification fails to provide one of skill in the art proper guidance, direction, or examples to make and use the claimed method and system.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8 and 10-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 7, 17, and all claims dependent therefrom recite the limitation "said biochips are sensitive for more biomolecular markers than said predetermined number of biomolecular markers..."/"a plurality of disposable biochips, each sensitive for multiple biomolecular markers..." which is vague and indefinite. The term "sensitive" implies some selection criteria/threshold value indicative of said biochips to be "sensitive" for multiple biomolecular markers. Applicants' can resolve this issue by particularly pointing out the selection criteria/threshold value that establishes a biochip to be "sensitive" and the criteria/threshold that establishes a biochip to be "sensitive for more biomolecular markers than said predetermined number of biomolecular markers, for example, instead of being "sensitive" for all biomolecular markers. Clarification of the metes and bounds, via clearer claim language is requested.

Claim 17 and all claims dependent therefrom recites the limitation "...creating a modified expert rule with improved diagnostic value in comparison to said expert rule used to produce said diagnostic result..." which is vague and indefinite. The above limitation implies a set of criteria that establishes the "modified expert rule" is an improvement in diagnostic value over that the said expert rule used to produce said diagnostic result. Applicants' response filed 08 December 2003 states:

"The "improvement" can be simply that the new diagnostic result is more precise Applicants' can resolve this issue by particularly pointing out the criteria that establishes the modified expert rule is indeed an improvement over that of said expert rule used to produce said diagnostic result. Clarification of the metes and bounds, via clearer claim language is requested.

OBJECTION TO CLAIMS

Claim 18 is objected to because of a typographical error on line 15, wherein "care sites;\" should be corrected to "care sites;". Appropriate correction is requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: May 17, 2004

Examiner Initials: CSM

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
5/17/04